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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,799	08/29/2003	Patricia B. Hoyer	241331US20	7462

22850 7590 10/19/2007

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/650,799	HOYER ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8-23,25,28-37 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *14-19 and 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,8-13,20-23,25,28-30,37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08). Paper No(s)/Mail Date *05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's reply filed on 08/02/2007 is acknowledged. Claims 1,11,12,23,25,37,41 have been amended. Claims 2,3,6,7,24,26-27,38-39, and 43-60 have been cancelled. Claims 14-19 and 31-36 are withdrawn. Claims 1,4,5,8-23,25,28-37, and 40-42 are pending and claims 1,4,5,8-13,20-23,25,28-30,37,40-42 are under consideration in the instant office action.

Information Disclosure Statement

Applicant states that a copy of the text of the poster listed as reference AAJ at page 4 on was submitted with Applicant's reply. However, such text has not been located by the Examiner. The reference is, therefore, not considered on the record.

Double Patenting

The double patenting warning is withdrawn in light of Applicant's cancellation of claim 45.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 40 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 37 and 40 is maintained for reasons of record set forth at pages 3-4 of the office action dated 06/01/2006. Applicant's arguments have been fully considered and are not found persuasive.

Claim 37 is unclear because the method steps of claim 37 fail to relate back to the preamble in a positive process. The claim does not recite what is indicative of the desired outcome or what assay should be performed to complete the method.

Applicant has amended the claims to remove the phrase "an effective amount" which was unclear as to what the compound must be effective in doing. However, the claim still fails to recite the outcome of the method.

The rejection of claims 38 and 45-47 is rendered moot by Applicant's cancellation of the claims.

Claims 23,25,28-30,41 and 42 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is unclear because the method steps fail to relate back to the preamble of the claim in a positive process. The claim is drawn to a method of controlling the size of an animal population. However, the body of the claim merely requires causing at least partial ovarian function in at least a portion of the female members of the population.

Claim 41 is further unclear because it fail to recite to what the VCD is administered.

Claim 42 depends from claim 41.

Claim 23 is unclear because, while referring to claim 1, it is drawn to a method and claim 1 is drawn to a product. Thus, the claim fails to relate back to the preamble in a positive process in that it does not require that any particular animal be obtained. It is not known whether the characteristics of menopause and/or perimenopause are required for the method.

Claims 25 and 28-30 depend from claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1) The rejection of claims 1,2,4-6,9-10,13,23,24 and 28-30 under 35 U.S.C. 102(a) as being anticipated by Mayer et al. (Abstract of Poster Presentation presented at the Mountain West Society for Toxicology Meeting, Taos New Mexico, September 2001, IDS) is withdrawn in light of Applicant's the Hoyer and Mayer declaration under 37 CFR 1.132 dated 11/21/2006 demonstrating that Mayer et al. is Applicant's own work.

2) The rejection of claims 1,2,4-6,9-13,23-25 and 28-30 under 35 U.S.C. 102(a) as being anticipated by Mayer et al. (Abstract of Poster Presentation presented at the Endocrinology Annual Meeting, San Francisco, CA, June 2002, IDS) is withdrawn in light of Applicant's the Hoyer and Mayer declaration under 37 CFR 1.132 dated 11/21/2006 demonstrating that Mayer et al. is Applicant's own work.

3) The rejection of claims 41 and 43 under 35 U.S.C. 102(b) as being anticipated by Acarturk (**Pharmaceutical Research**, 13:779-789, 1996) is withdrawn.

4) Claims 1,4,5,9-12,13, and 20 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Kao et al (1999, IDS) as evidenced by Amant [2001, **Circulation**, 104:2576-2581] and Osei-Hyiaman (1998, **Am Jour Epidem**, 148:1055-1061).

Kao et al. taught administering 80 mg/kg/day of VCD to cause characteristics of ovarian failure in mice and rats. Kao taught that mice appear to be more susceptible than rats to the ovotoxic effects of

VCD. Kao taught a significant loss of ovarian primordial follicles (page 69, col. 2). Loss of ovarian primordial follicles is a characteristic of peri-menopause and menopause. Kao et al. did not teach use of a dosage of at least 100mg/kg/day. However, the animals resulting from the use of 80 mg/kg/day appear to be the same as those treated with 100mg/kg/day. It is noted that:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best,* 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

In the instant case, there is no evidence of record to indicate that the animals made in the art differ in structure from those claimed.

It is also noted that the claims are product by process claims in which the process of creating the animal carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a menopausal or perimenopausal animal) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed menopausal/perimenopausal female animals are met by any menopausal or perimenopausal animals in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Claims 11 and 12 are anticipated as set forth above and as evidenced by Amant. Amant states the art-accepted fact that 17β-estradiol levels are erratic and then diminished through perimenopause and menopause.

Claim5 is anticipated as set forth above and as evidenced by Osei-Hyiaman. Osei-Hyiaman states the art-accepted fact that there is a decrease in bone mineral density associated with menopause.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) The rejection of claims 1 and 20 under 35 U.S.C. 103(a) as being unpatentable over Kao et al (1999, IDS) in view of Mayer et al. (2001, IDS) or Mayer et al (2002, IDS) is withdrawn in light of Applicant's the Hoyer and Mayer declaration under 37 CFR 1.132 dated 11/21/2006 demonstrating that Mayer et al. is Applicant's own work.

2) The rejection of claims 1 and 21 under 35 U.S.C. 103(a) as being unpatentable over Abel *et al.* (**Jour Clin Endocrin Metab,** 84:2111-2118, 1999) in view of Mayer et al. (2001, IDS) or Mayer et al (2002, IDS) and further in view of Judd (1976, IDS) is withdrawn in light of Applicant's the Hoyer and Mayer declaration under 37 CFR 1.132 dated 11/21/2006 demonstrating that Mayer et al. is Applicant's own work.

3) The rejection of claims 37,38,41-43 and 45-47 under 35 U.S.C. 103(a) as being unpatentable over Acarturk (Pharmaceutical Research, 13:779-789, 1996) in view of Kao et al. (1999, IDS) and further in view of Judd (1976, IDS) is withdrawn in light of Applicant's the Hoyer and Mayer declaration under 37 CFR 1.132 dated 11/21/2006 demonstrating that Mayer et al. is Applicant's own work.

4) Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al (1999, IDS) in view of Abel *et al.* (Jour Clin Endocrin Metab, 84:2111-2118, 1999) and further in view of Judd (1976, IDS).

Claim 1 is drawn to a mammalian non-human female having at least partial depletion of the ovarian primordial follicles and at least one characteristic of menopause or perimenopause induced by administration of VCD at a dosage of 100mg/kg/day. Claim 21 limits the animal to a primate.

Kao et al. taught administering 80 mg/kg/day of VCD to cause characteristics of ovarian failure in mice and rats. Kao taught that mice appear to be more susceptible than rats to the ovotoxic effects of VCD. Kao taught a significant loss of ovarian primordial follicles (page 69, col. 2). Loss of ovarian primordial follicles is a characteristic of peri-menopause and menopause.

Kao did not teach applying the method of inducing menopausal or perimenopausal symptoms in primates.

However, Abel taught use of primates in generating animal models of menopause by ovarectomy for use in testing hormone replacement therapy.

Furthermore, Judd, taught that ovarectomy is not the best model of menopause as it lacks the hormonal regulation of the postmenopausal ovary as evidence by differences in hormone levels of normal postmenopausal women and women who have undergone ovarectomy.

Therefore, it would have been obvious to combine the teachings of Kao and Abel to make a primate model of menopause to study human post-menopausal hormone replacement therapies as taught by Abel by substituting ovarectomy with VCD treatment as taught by Kao. One of skill in the art would be motivated to induce menopause in primates using VCD rather than ovarectomy because Judd taught that ovarectomy was not an exact model of menopause as it remove the active influences and functions of the post-menopausal ovary.

While neither Kao, Abel nor Judd taught administering VCD at a dosage of 100mg/kg/day to induce menopause as claimed, the animals resulting from the use of 80 mg/kg/day appear to be the same as those treated with 100mg/kg/day. It is noted that:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best,* 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

In the instant case, there is no evidence of record to indicate that the animals made in the art differ in structure from those claimed.

It is also noted that the claims are product by process claims in which the process of creating the animal carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a menopausal or perimenopausal animal) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed menopausal/perimenopausal female animals are met by any menopausal or perimenopausal animals in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

One of skill in the art would have had a reasonable expectation of success in applying the method of Kao to primates because primates are similar to mice in the anatomical and physiological processes that occur before and after the onset of menopause.

Thus, the claimed invention is clearly prima facie obvious in the absence of evidence to the contrary.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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primordial follicles is a characteristic of peri-menopause and menopause. Kao et al. did not teach use of a dosage of at least 100mg/kg/day. However, the animals resulting from the use of 80 mg/kg/day appear to be the same as those treated with 100mg/kg/day. It is noted that:

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Kao did not teach applying the method of inducing menopausal or perimenopausal symptoms in primates.

However, Abel taught use of primates in generating animal models of menopause by ovarectomy for use in testing hormone replacement therapy. Furthermore, Judd, taught that ovarectomy is not the best model of menopause as it lacks the hormonal regulation of the postmenopausal ovary as evidence by differences in hormone levels of normal postmenopausal women and women who have undergone ovarectomy.

Therefore, it would have been obvious to combine the teachings of Kao and Abel to make a primate model of menopause to study human post-menopausal hormone replacement therapies as taught by Abel by substituting ovarectomy with VCD treatment as taught by Kao. One of skill in the art would be motivated to induce menopause in primates using VCD rather than ovarectomy because Judd taught that ovarectomy was not an exact model of menopause as it remove the active influences and functions of the post-menopausal ovary.

While neither Kao, Abel nor Judd taught administering VCD at a dosage of 100mg/kg/day to induce menopause as claimed, the animals resulting from the use of 80 mg/kg/day appear to be the same as those treated with 100mg/kg/day. It is noted that:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best,* 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

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It is also noted that the claims are product by process claims in which the process of creating the animal carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a menopausal or perimenopausal animal) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed menopausal/perimenopausal female animals are met by any menopausal or perimenopausal animals in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

One of skill in the art would have had a reasonable expectation of success in applying the method of Kao to primates because primates are similar to mice in the anatomical and physiological processes that occur before and after the onset of menopause.

Thus, the claimed invention is clearly prima facie obvious in the absence of evidence to the contrary.

5) Claims 1 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al (1999, IDS) in view of Mulholland *et al.* (**Jour Urol**, 1982, 127:1010-1013) and further in view of Judd (1976, IDS).

Claim 1 is drawn to a mammalian non-human female having at least partial depletion of the ovarian primordial follicles and at least one characteristic of menopause or perimenopause induced by administration of VCD at a dosage of 100mg/kg/day. Claim 22 limits the animal to a canine.

Kao et al. taught administering 80 mg/kg/day of VCD to cause characteristics of ovarian failure in mice and rats. Kao taught that mice appear to be more susceptible than rats to the ovotoxic effects of VCD. Kao taught a significant loss of ovarian primordial follicles (page 69, col. 2). Loss of ovarian primordial follicles is a characteristic of peri-menopause and menopause.

Kao did not teach applying the method of inducing menopausal or perimenopausal symptoms in canine.

However, Mulholland taught use of canine in generating animal models of menopause by oophorectomy for use in making a postmenopausal female model.

Judd, taught that ovarectomy is not the best model of menopause as it lacks the hormonal regulation of the postmenopausal ovary as evidence by differences in hormone levels of normal postmenopausal women and women who have undergone ovarectomy.

Therefore, it would have been obvious to combine the teachings of Kao and Mulholland to make a canine model of menopause to study human post-menopausal hormone replacement therapies as taught by Mulholland by substituting ovarectomy with VCD treatment as taught by Kao. One of skill in the art would be motivated to induce menopause in primates using VCD rather than ovarectomy because Judd taught that ovarectomy was not an exact model of menopause as it remove the active influences and functions of the post-menopausal ovary.

While neither Kao, Mulholland nor Judd taught administering VCD at a dosage of 100mg/kg/day to induce menopause as claimed, the animals resulting from the use of 80 mg/kg/day appear to be the same as those treated with 100mg/kg/day. It is noted that:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best,* 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

In the instant case, there is no evidence of record to indicate that the animals made in the art differ in structure from those claimed.

It is also noted that the claims are product by process claims in which the process of creating the animal carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a menopausal or perimenopausal animal) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed menopausal/perimenopausal female animals are met by any menopausal or perimenopausal animals in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

One of skill in the art would have had a reasonable expectation of success in applying the method of Kao to canine because canine are similar to mice in the anatomical and physiological processes that occur before and after the onset of menopause.

Thus, the claimed invention is clearly prima facie obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Valarie Bertoglio, Ph.D./
Primary Examiner
Art Unit 1632